IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
HOT SPRINGS DIVISION

MARILYN STUBE and
THOMAS STUBE PLAINTIFFS

v. Case No. 6:19-cv-6087

PFIZER INC. DEFENDANT

ORDER

Before the Court is Defendant Pfizer Inc.'s Motion to Dismiss. (ECF No. 18). Plaintiffs Marilyn Stube and Thomas Stube filed a response. (ECF No. 22). Defendant filed a reply. (ECF No. 25). The Court finds the matter ripe for consideration.

I. BACKGROUND

This is a personal injury and products liability case allegedly arising from Plaintiff Marilyn Stube's ("Mrs. Stube") alleged ingestion of Defendant's prescription drug, Xeljanz (tofacitinib).[1] In December 2011, Defendant applied for the United States Food and Drug Administration's ("FDA") approval of Xeljanz for use by adult patients with moderate to severe active rheumatoid arthritis. On November 6, 2012, the FDA approved the Xeljanz application.

On March 14, 2013, Mrs. Stube was prescribed Xeljanz and she ingested it until the time of her injuries. On March 24, 2017, Mrs. Stube presented at the CHI St. Vincent Hospital in Hot Springs, Arkansas, complaining of shoulder pain after moving a kayak. She was discharged with an arm sling and, four days later, returned to the hospital with complaints of chronic pain, fever, nausea, vomiting, and shortness of breath. After admitting her, hospital staff instructed her to stop

[1] As Plaintiffs describe it, Xeljanz "is an oral Janus kinase inhibitor approved for the treatment of adult patients with moderate to severe active rheumatoid arthritis, active psoriatic arthritis, and moderate to severely active ulcerative colitis." (ECF No. 2, p. 2).

taking Xeljanz. The next day, she experienced septic shock due to Streptococcus Group A infection and ultimately experienced multi-organ failure, gangrene, and amputation of all four of her limbs.

On July 18, 2019, Plaintiffs brought this lawsuit, asserting that Mrs. Stube's injuries were the direct result of her having taken Xeljanz and Defendant's failure to adequately warn of the risks thereof. Plaintiffs assert six state law causes of action: (1) strict products liability/failure to warn; (2) fraud and fraudulent inducement; (3) breach of implied warranty; (4) negligence; (5) negligent misrepresentation; and (6) gross negligence. Plaintiffs seek various forms of relief, including punitive damages.

On September 9, 2019, Defendant filed the instant motion to dismiss, contending that Plaintiffs' claims should be dismissed on various grounds pursuant to Federal Rules of Civil Procedure 8(a)(2), 9(b), and 12(b)(6). Plaintiffs oppose the motion.

II. STANDARD

A party may move to dismiss for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). To survive a motion to dismiss under Rule 12(b)(6), a pleading must provide "a short and plain statement of the claim that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The purpose of this requirement is to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The factual allegations of a complaint are assumed true and all reasonable inferences are drawn in the plaintiff's favor, "even if it strikes a savvy judge that actual proof of those facts is improbable." *Twombly*, 550 U.S. at 555-56. A court, however, need not "blindly accept the legal conclusions drawn by the pleader from the facts." *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990).

The complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' Nor does a complaint suffice if it tenders 'naked assertions' devoid of 'further factual enhancement.'" *Id.* (internal citations and alterations omitted) (quoting *Twombly*, 550 U.S. at 555, 557). In other words, "the pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* (quoting *Twombly*, 550 U.S. at 555).

Additionally, claims sounding in fraud must comply with the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) by pleading with particularity the circumstances surrounding the fraud. *United States ex rel. Costner v. United States*, 317 F.3d 883, 888 (8th Cir. 2003). This pleading standard "demands a higher degree of notice than that required for other claims. The claim must identify who, what, where, when, and how." *Id.*

III. DISCUSSION

Defendant argues that Plaintiffs' claims should be dismissed pursuant to Rules 8(a)(2), 9(b), and 12(b)(6). Defendant argues that Plaintiffs' claims should all be dismissed for two reasons: (1) the Xeljanz label adequately warned of the injury Mrs. Stube suffered and (2) federal law preempts Plaintiffs' claims. Failing that, Defendant argues that Plaintiffs' claims should be partially dismissed because: (1) they are barred by the learned intermediary doctrine to the extent that they are based on Defendant's alleged failure to warn Mrs. Stube rather than her prescribing physician; (2) Plaintiffs fail to state a claim upon which relief may be granted for fraud, negligent

misrepresentation, and gross negligence; and (3) the complaint's allegations do not support an award of punitive damages.

The Court must begin by first addressing the exhibits offered by the parties in their briefing of the instant motion. After that, the Court will address Defendant's arguments for complete dismissal and, if necessary, will then take up the arguments for dismissal of certain claims.

A. The Parties' Exhibits

Defendant's motion is accompanied by 5 exhibits, totaling 359 pages.[2] Plaintiffs' response brief is accompanied by 9 exhibits, totaling 225 pages. The Court must decide whether to consider these exhibits before turning to the substance of Defendant's motion.

The purpose of a Rule 12(b)(6) motion is to test the legal sufficiency of the complaint, so the Court's inquiry is limited to whether the challenged pleading sets forth sufficient allegations to make out the elements of a right to relief. *Peck v. Hoff*, 660 F.2d 371, 374 (8th Cir. 1981). To decide this, the Court must ordinarily confine its analysis to the four corners of the complaint and ignore all materials outside the pleadings. *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999). However, the Court may consider "some materials that are part of the public record or do not contradict the complaint . . . as well as materials that are necessarily embraced by the pleadings." *Id.* (internal quotation marks omitted).

Defendant suggests that the Court may consider its exhibits because they are available on the FDA's website and, thus, the Court may take judicial notice of them, presumably because the

[2] Although expressly not offered as exhibits, Defendant also cites to various websites and medical studies throughout its supporting brief.

exhibits are part of the public record.[3] Plaintiffs do not argue that their exhibits fall within any of the limited exceptions of extrinsic evidence that may be considered on a Rule 12(b)(6) motion.

"Most courts . . . view 'matters outside the pleading[s]' as including any written or oral evidence in support of or in opposition to the pleading that provides some substantiation for and does not merely reiterate what is said in the pleadings." *Gibb v. Scott*, 958 F.2d 814, 816 (8th Cir. 1992). This "broad interpretation" is "appropriate in light of [the Eighth Circuit's] prior decisions indicating a Rule 12(b)(6) motion will succeed or fail based upon the allegations contained in the face of the complaint." *Id.*

It is certainly arguable that at least some of the parties' exhibits are "matters outside the pleadings" that cannot be considered in a Rule 12(b)(6) analysis. The parties offer exhibits in support of their respective positions, providing some substantiation for or against the complaint. Thus, the Court's reading of *Gibb* would suggest that the parties' exhibits cannot be considered at this stage. *Id.*

However, the Court does not need to answer that question because, assuming without deciding that the parties' exhibits can all be considered on a Rule 12(b)(6) motion, the Court declines to do so. The Court enjoys "complete discretion to determine whether or not to accept any material beyond the pleadings that is offered in conjunction with a Rule 12(b)(6) motion." *Stahl v. U.S. Dept. of Agric.*, 327 F.3d 697, 701 (8th Cir. 2003); *Skyberg v. United Food & Commercial Workers Int'l Union*, 5 F.3d 297, 302 n.2 (8th Cir. 1993). Thus, even if extrinsic

[3] Defendant cites to a Report and Recommendation authored by a United States Magistrate Judge who, at the summary judgment stage, took *sua sponte* judicial notice of the Mayo Clinic and the National Institute of Health's websites for use in expository footnotes. That Report and Recommendation was not objected to and was subsequently adopted by another judge in this district. *See Giddings v. Cradduck*, No. 5:16-cv-5035-TLB/ELW, 2017 WL 2791345, at *6-7 n.4, 5 (W.D. Ark. Jun. 6, 2017), *report and recommendation adopted*, 2017 WL 2799297 (W.D. Ark. Jun. 27, 2017). To the extent that Defendant contends that its exhibits are not part of the public record but that the Court should nonetheless take judicial notice of them, the Court declines because it is not bound by *Giddings*. *See Se. Stud & Components, Inc., v. Am. Eagle Design*, 588 F.3d 963, 967 (8th Cir. 2009) ("[O]ne district court is not bound by the holdings of others, even those within the same district.").

evidence falls within one of the limited exceptions of evidence that may be considered on a Rule 12(b)(6) motion, the Court may choose to not consider it. *Navarro v. Am. Nat'l Skyline Inc. of Mo.*, No. 4:12-cv-801 HEA, 2013 WL 1342999, at *2 (E.D. Mo. Apr. 3, 2013).

As stated above, the purpose of a Rule 12(b)(6) motion is to test the sufficiency of the complaint. The Court does this by deciding whether the complaint sets forth sufficient allegations to make out the elements of a right to relief. *Peck*, 660 F.2d at 374. To the extent that Defendant's Rule 12(b)(6) arguments require the Court to look beyond the four corners of the complaint and consider approximately 584 pages of extrinsic evidence, those arguments are better suited for the summary judgment stage. Consequently, the Court will not consider any of the parties' exhibits and will instead confine its analysis to the four corners of Plaintiffs' complaint.

B. Adequacy of the Xeljanz Label's Warnings

Defendant contends that Plaintiffs' entire complaint fails as a matter of law and should be dismissed because the label included with Xeljanz during the relevant period put prescribing physicians on notice that patients taking the drug would be at an increased risk for serious infections and that such infections could lead to hospitalization.[4] Plaintiffs argue that they alleged that the Xeljanz label provided insufficient warning regarding the risk of sepsis, amputations, and infections, particularly in the elderly, in females, and in those who have herpes zoster (also known as shingles)—all subpopulations that Mrs. Stube fell under. Thus, they contend that Defendant's Xeljanz label provided an inadequate warning. Plaintiffs also suggest that the adequacy of the Xeljanz warning label should not be decided at the pleading stage.

[4] Although a drug's "label" is commonly understood to refer to the sticker affixed to a prescription bottle, "in this context the term refers more broadly to the written material that is sent to the physician who prescribes the drug and the written material that comes with the prescription bottle when the drug is handed to the patient at the pharmacy. These (often lengthy) package inserts contain detailed information about the drug's medical uses and health risks." *Merck Sharp & Dohme Corp. v. Albrecht*, ___ U.S. ___, 139 S. Ct. 1668, 1672-73 (2019) (internal citations omitted).

A federal court sitting in diversity, like the Court in this case, must apply the substantive law of the forum state, absent a federal statutory or constitutional directive to the contrary. *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938); *Blankenship v. USA Truck, Inc.*, 601 F.3d 852, 856 (8th Cir. 2010). The Court is unaware of a federal statutory or constitutional directive providing otherwise, so Arkansas substantive law applies to this case. "Under Arkansas law, a drug warning is adequate so long as it puts a reasonably prudent physician on notice of a particular risk that the manufacturer has actual or constructive knowledge of at the time of distribution." *Bell v. Pliva, Inc.*, 845 F. Supp. 2d 967, 970 (E.D. Ark. 2012) (citing *In re Prempro Prods. Liab. Litig.*, 514 F.3d 825, 830 (8th Cir. 2008)), *rev'd in part on other grounds*, *Bell v. Pfizer, Inc.*, 716 F.3d 1087 (8th Cir. 2013).

Defendant provides the Court with the box warning that was purportedly included with Xeljanz during the relevant period and argues that the contents thereof were adequate to warn Mrs. Stube's prescribing physician of the risks of Xeljanz. In further support of that assertion, Defendant cites to various websites discussing sepsis, which Defendant contends is a well-known consequence of infection, rather than a medically distinct condition. Defendant also cites to several medical journal studies that purportedly refute Plaintiffs' allegations of data indicating that elderly females who take Xeljanz are at heightened risk of serious infection. Defendant further cites to various letters and reports from the FDA for the proposition that the Xeljanz warning label was adequate because it had been approved by the FDA.

The problem with these arguments is that they require the Court to look beyond the four corners of the pleadings and consider a host of other sources, which the Court has already determined it will not do at this stage. Looking solely at the complaint, Plaintiffs allege, in relevant part, that Defendant's Xeljanz label provided an inadequate warning as it relates to the heightened

risk of sepsis in elderly women taking Xeljanz, despite Defendant's knowledge of the same. Plaintiffs also allege that Mrs. Stube's prescribing physician relied on the warning provided by Defendant regarding the safety of Xeljanz and that, had he known the full extent of the risks someone like Mrs. Stube would face from taking Xeljanz, he would not have prescribed it to her.

Plaintiffs' allegations, taken as true, are enough at this stage to make out a viable failure-to-warn claim. The Court will not weigh evidence or assess credibility at this point. Consequently, the Court finds that the instant motion should be denied to the extent that it seeks dismissal of all claims on the basis that the Xeljanz warning label was adequate as a matter of law.

C. Whether Federal Law Preempts Plaintiffs' Claims

Next, Defendant argues that all of Plaintiffs' claims should be dismissed because they are preempted by federal law under the doctrine of impossibility preemption, a type of conflict preemption. Plaintiffs disagree.

The doctrine of preemption arises from the Supremacy Clause of the United States Constitution, which requires that state law must give way when it conflicts with or frustrates federal law. U.S. Const. art. VI, cl. 2.; *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 663 (1993). "Thus, state law that conflicts with federal law has no effect." *Jones v. Vilsack*, 272 F.3d 1030, 1033 (8th Cir. 2001). With one exception not relevant to this case, preemption is an affirmative defense.[5] *Chapman v. Lab One*, 390 F.3d 620, 624-25 (8th Cir. 2004).

"Whether a particular federal statute preempts state law depends upon congressional purpose." *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.*, 621 F.3d 781,

[5] Ordinarily, federal preemption is merely a defense to a state-law claim and does not alter or confer a federal court's jurisdiction. *See Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 63 (1987). However, when an area of state law has been "completely preempted," any claim "purportedly based on that pre-empted state law is considered, from its inception, a federal claim, and therefore arises under federal law." *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 393 (1987). As such, complete preemption of a state-law cause of action provides a basis for removal of the action to federal court. Defendant does not argue that complete preemption has any application here, so the Court will not consider it.

791 (8th Cir. 2010). In determining the congressional intent behind a statute, courts may consider the statute itself and any regulations enacted pursuant to the statute's authority. *See U.S. Dep't of Justice v. Reporters Comm. for Freedom of Press*, 489 U.S. 749, 765 (1989).

State law can be either expressly or impliedly preempted by federal law. *Cipollone v. Liggett Group*, 505 U.S. 504, 516 (1992). As stated above, Defendant argues that Plaintiffs' claims are impliedly preempted by federal law, specifically, by the doctrine of conflict preemption. *Id.* Conflict preemption, as relevant to this case, "exists where a party's compliance with both federal and state law would be impossible." *Pet Quarters, Inc. v. Depository Trust & Clearing Corp.*, 559 F.3d 772, 780 (8th Cir. 2009). Impossibility preemption "is a demanding defense." *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 939 (8th Cir. 2011). With respect to "the historic primacy of state regulation of matters of health and safety," there is a general presumption against finding implied preemption absent a clear congressional intent. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *see also Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 885 (2000) ("[A] court should not find pre-emption too readily in the absence of clear evidence of a conflict.").

Defendant argues that Plaintiffs' state-law claims—which are all predicated on Defendant's alleged failure to provide an adequate warning of Xeljanz's risks—are preempted by the Food, Drug, and Cosmetic Act of 1983 (the "FDCA") and FDA regulations promulgated pursuant to it. Defendant asserts that, pursuant to the FDCA, once the FDA approved the Defendant's proposed label for Xeljanz, Defendant could not later unilaterally change the label to include additional warnings. Thus, Defendant argues that Plaintiffs' claims are preempted by federal food and drug laws because it was impossible for Defendant to comply with both its federal labeling duties and the state-law duty to warn.

Plaintiffs respond by organizing their claims into two types: pre-approval failure to warn and post-approval failure to warn. In other words, their claims can be broken down into two distinct contentions: (1) that Defendant should have included additional warnings in its initial proposed label during the FDA approval process and (2) that Defendant should have sought the FDA's approval to add new warnings after the initial label was approved. Plaintiffs argue that neither type of claim is preempted. For their pre-approval claims, they argue that it is not impossible for a drug manufacturer to comply with both federal and state law before submitting a new drug application to the FDA for approval. For the post-approval claims, they argue that federal regulations allow a drug manufacturer to unilaterally change a warning label based on newly acquired information and, thus, it was not impossible for Defendant to comply with both federal and state law by amending the label after FDA approval had been granted.

The "state law" to be considered in cases of federal preemption includes not only state statutes and regulations, but also a state's tort law. *Geier*, 529 U.S. at 886. It is undisputed that in Arkansas, a manufacturer generally must "warn . . . of the risks of its product. This duty exists under either . . . negligence or strict liability theories." *West v. Searle & Co.*, 305 Ark. 33, 42, 806 S.W.2d 608, 613 (1991). Thus, Defendant had a duty under Arkansas law to adequately warn of the risks of taking Xeljanz. The question now becomes whether Plaintiffs' claims, all of which are predicated on that state-law duty to warn, are preempted by federal food and drug law. To determine this, the Court must examine Congress' purpose and intent in enacting the FDCA, which regulates the manufacture and sale of prescription drugs. *Merck KGAA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 (2005). In doing so, the Court may "consider the statute itself and any regulations enacted pursuant to the statute's authority." *In re Aurora*, 621 F.3d at 792.

The FDCA requires that drug manufacturers obtain the FDA's approval before marketing or selling a drug in interstate commerce. *See* 21 U.S.C. § 355(a). The FDA drug-approval process is "onerous and lengthy." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013). In short, "a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011)

To gain FDA approval, a drug manufacturer must submit a new-drug application ("NDA"). *See* 21 C.F.R. § 314.1 et seq. The NDA must include "full reports of [all clinical] investigations which have been made to show whether . . . such drug is effective in use." 21 U.S.C. § 355(b)(1)(A). The FDA will only approve the drug if the NDA provides "substantial evidence that the drug will have the effect it . . . is represented to have." 21 U.S.C. § 355(d)(5). To show "substantial evidence" of a drug's effects, a manufacturer must submit, *inter alia*, the results of "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved." 21 U.S.C. § 355(d)(7).

The drug manufacturer must also submit "the labeling proposed to be used for such drug." 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. § 314.50(c)(2)(i). The application must include the proposed label's text "with annotations to the information in the [application] that support the inclusion of each statement [on the label]." 21 C.F.R. § 314.50(c)(2)(i). Before approving an NDA, the FDA must determine, "based on a fair evaluation of all material facts," that the proposed label is not "false or misleading in any particular." 21 U.S.C. § 355(d)(7); 21 C.F.R. § 314.125(b)(6). After the FDA approves a proposed label, the manufacturer may market and distribute the drug without

violating federal law so long as it uses the exact FDA-approved label. *See* 21 U.S.C. §§ 331(c), 333(a), & 352(a), (c).

"Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application." *Wyeth v. Levine*, 555 U.S. 555, 568 (2009). However, the so-called "Changes Being Effected" ("CBE") regulation allows a drug manufacturer to immediately change a warning label, without FDA approval, based on newly acquired information to, among other things, "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product."[6] 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C). "Newly acquired information" is defined as follows for purposes of the CBE regulation:

> [D]ata, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 314.3(b). "Information previously known to the manufacturer, but not submitted to the FDA, may constitute 'newly acquired information,' provided that the information meets the other CBE requirements." *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 659 (S.D.N.Y. 2017), *aff'd sub nom. Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019). The CBE regulation "accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments." *Levine*, 555 U.S. at 569.

[6] The FDA subsequently reviews labeling changes made pursuant to the CBE regulation and retains authority to reject any such change, requiring the drug manufacturer to revert to using the FDA-approved label. *Wyeth*, 555 U.S. at 571. If the FDA does nothing, the label change remains in effect. *See* 56 Fed. Reg. 59290 (Nov. 25, 1991).

Keeping this framework in mind, the Court will begin by addressing whether Plaintiffs' pre-approval claims are preempted. Then the Court will address Plaintiffs' post-approval claims.

1. Pre-Approval Claims

Plaintiffs argue that it was possible for Defendant to simultaneously comply with its federal labeling duties and its duty to adequately warn of Xeljanz's risks because it could have initially applied for FDA approval of a stronger warning label. Defendant argues that Plaintiffs' pre-approval claims are preempted because the FDA approved the initial warning label submitted by Defendant and, thus, Defendant could not change the label.

The Court finds Defendant's argument unavailing because the crux of Plaintiffs' pre-approval claim is that Defendant could and should have submitted a stronger initial label for FDA consideration during the NDA approval process. As several federal district courts have stated, "[a]lthough defendants are correct in stating the labeling language must not deviate from that which was approved by the FDA, defendants still possessed the ability to implement stronger warning language into labeling . . . by submitting stronger warning language for [initial] FDA approval." *Holley v. Gilead Scis., Inc.*, 379 F. Supp. 3d 809, 826 (N.D. Cal. 2019) (quoting *In re Actos (Pioglitazone) Prods. Liab. Litig.*, No. 12-cv-00064, 2014 WL 60298, at *7 (W.D. La. Jan. 7, 2014)).

Certain courts have interpreted the Supreme Court's opinion in *Wyeth v. Levine*, 555 U.S. 555 (2009), as barring claims "based on information available at the commencement of marketing, while allowing the states to reach contrary conclusions when new information not considered by the FDA develops." *See, e.g., In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015). "Although, as discussed below, the question of what information was presented to the FDA is relevant in the post-approval context, the Court does not read *Levine* as

requiring preemption of all failure-to-warn claims, including pre-approval claims, based on material that has been presented to the FDA."[7] *Holley*, 379 F. Supp. 3d at 826.

As part of the FDA approval process, manufacturers must submit a proposed drug label that contains certain information. *See* 21 U.S.C. § 355(b)(1)(F) (listing requirements); 21 C.F.R. § 314.50(c)(2)(i) (same). So long as a new drug application contains that required information, the Court fails to see how compliance with the FDA approval process would present an impossible conflict with Arkansas's duty to warn. A manufacturer could propose a more strongly worded label for the FDA to consider so long as the proposed label also contains the other requisite information.

Therefore, Defendant has not shown that it was impossible to comply with both state and federal law and regulations prior to submitting its Xeljanz application to the FDA for initial approval. Bearing in mind the "general presumption against finding implied preemption absent a clear congressional intent," *Lohr*, 518 U.S. at 485, the Court finds that Defendant has failed to show that Plaintiffs' pre-approval failure to warn claims are preempted.

B. Post-Approval Claims

The Court must now determine whether Plaintiffs' post-approval claims are preempted. There is no dispute that, once the FDA approved the Xeljanz label, Defendant generally could not change the label without obtaining further FDA approval. However, it is also undisputed that the CBE regulation allowed Defendant to change the label without first obtaining FDA approval if newly acquired information existed that revealed "risks of a different type or greater severity or

[7] *Levine* held that federal law did not impliedly preempt a failure to warn claim brought against a drug manufacturer because the CBE regulation permitted the manufacturer to update its label with newly acquired information and there was insufficient evidence that the FDA would have refused such an update. *Levine*, 555 U.S. at 571. *Levine* focused "exclusively on what a drug manufacturer could do post-FDA approval to enhance the warnings of serious risks in the labeling of its product . . . [and] did not address whether a state law failure to warn claim addressed to the NDA process was preempted." *Utts*, 226 F. Supp. 3d at 180.

frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3(b). The CBE regulation underscores the well-established premise that a drug manufacturer is not only charged "with crafting an adequate label" as an initial matter, but also "with ensuring that its warnings remain adequate as long as the drug is on the market." *Levine*, 555 U.S. at 571. Of course, the FDA retains the authority to review labeling changes made pursuant to the CBE regulation and to reject any such change, thereby requiring the drug manufacturer to revert to using the old label. *Id.*

Thus, the answer to the post-approval preemption question depends on a two-part inquiry. For Plaintiffs' post-approval claims to not be preempted, they must allege that newly acquired information existed such that Defendant could have unilaterally changed the Xeljanz label in accordance with the CBE regulation. *Id.* at 569-71. Then, even if Plaintiffs alleged the existence of newly acquired information, Defendant may still establish an impossibility preemption defense by showing by "clear evidence" that the FDA would have subsequently rejected the labeling change made under the CBE regulation. *Id.* at 571.

Plaintiffs maintain that they alleged a litany of newly acquired information that would have allowed Defendant to amend the Xeljanz label under the CBE regulation. Plaintiffs also contend that Defendant cannot show by clear evidence that the FDA would have rejected such a label change. Conversely, Defendant contends that Plaintiffs have not alleged the existence of any newly acquired information, as defined for purposes of the CBE regulation. Defendant offers no argument on the issue of whether the FDA would have rejected a CBE regulation label change, contending that the Court need not reach that question because Plaintiffs failed to allege newly acquired information.

Taking all of Plaintiffs' well-pleaded allegations as true, the Court finds that the first step of the preemption analysis is satisfied. Plaintiffs have sufficiently alleged that newly acquired information existed such that Defendant could have used the CBE regulation to change its Xeljanz label. Defendant argues that Plaintiffs' allegations regarding newly acquired information are too conclusory to suffice, but the Court disagrees. Plaintiffs allege that, after the FDA approved the Xeljanz label on November 6, 2012, Defendant became aware of several medical studies, trials, and analyses reporting heightened incidence rates of infection, sepsis, and death in elderly and female subpopulations who ingest Xeljanz. Plaintiffs also allege that, post-approval, Defendant became aware of several medical studies, trials, and analyses reporting a higher incidence rate of patients developing herpes zoster after taking Xeljanz, which was much higher than previously known. Further, Plaintiffs allege that, post-approval, Defendant became aware of 47,287 adverse events related to ingestion of Xeljanz—257 of which involved sepsis, with 55 of those resulting in death; 34 of which involved septic shock, with 16 of those resulting in death; 1,214 of which involved herpes zoster, with 7 of those resulting in death; 14 to 16 of which involved amputations; and 5 of which involved gangrene, with 1 of those resulting in death. Plaintiffs alleged that none of the above information had been previously disclosed to the FDA. Thus, they argue that the above information constitutes newly acquired information, thereby giving Defendant the ability to utilize the CBE regulation to change the Xeljanz label.

The Court agrees. Plaintiffs have alleged the existence of newly acquired information that showed risks of taking Xeljanz that were of a different or greater severity or frequency than what had been previously disclosed to the FDA. Defendant points to various medical journals and argues that infection and sepsis are not medically distinct conditions and that sepsis is instead a well-known consequence of infection. Defendant contends that because it disclosed the risk of

infection in the Xeljanz label, any subsequent information arising related to sepsis does not constitute newly acquired information. As the Court discussed in the previous section, the Court declines to consider any extrinsic documents or weigh evidence at this time. Defendant may reassert this argument at the summary judgment stage. Taking the well-pleaded allegations as true, as the Court must do at this stage, the Court is satisfied that the CBE regulation was available to Defendant post-approval and that the first step of the inquiry has been satisfied.

Moving to the second step of the inquiry, Plaintiffs argue that Defendant cannot show that the FDA would have rejected any change to the Xeljanz label made under the CBE regulation. Defendant offers no argument or allegation stating otherwise. Thus, at this time, the Court cannot find clear evidence that the FDA would have rejected a change to the Xeljanz label made pursuant to the CBE regulation. Thus, Defendant has not shown that it was impossible for it to comply with both its federal labeling duties and its state law duty to warn. Consequently, Defendant has failed to show that Plaintiffs' post-approval claims are preempted.

D. Learned Intermediary Doctrine

Turning now to Defendant's arguments for partial dismissal, Defendant argues that the learned intermediary doctrine bars Plaintiffs' claims to the extent that they are predicated on Defendant's alleged duty to warn Plaintiffs, or the public, of the risks of taking Xeljanz. Plaintiffs disagree.

"As a general rule, a manufacturer has a duty to warn the ultimate user of the risks of its product. This duty exists under either . . . negligence or strict liability theories." *West*, 305 Ark. at 42, 806 S.W.2d at 613 (1991). However, Arkansas recognizes the so-called learned intermediary doctrine, which provides an exception to the general duty to warn. *Kowalski v. Rose Drugs of Dardanelle, Inc.*, 2011 Ark. 44, at 16, 378 S.W.3d 109, 120 (2011). Under the learned

intermediary doctrine, "a drug manufacturer may rely on the prescribing physician to warn the ultimate consumer of the risks of a prescription drug. The physician acts as the 'learned intermediary' between the manufacturer and the ultimate consumer." *Id.* (quoting *West*, 305 Ark. at 42, 806 S.W.2d at 613). "As such, a warning to the physician is deemed a warning to the patient." *In re Prempro*, 514 F.3d at 830 (applying Arkansas's learned intermediary doctrine). In other words, "adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly." *Id.*

Defendant argues that Plaintiffs' claims are barred by the learned intermediary doctrine to the extent that they are premised on Defendant's alleged duty to warn Mrs. Stube, or the public, of the risks of taking Xeljanz, rather than a duty to warn Mrs. Stube's prescribing physician of the risks of taking Xeljanz. Plaintiffs respond that their claims should not be dismissed on this basis because Defendant sent advertising materials and safety information directly to Mrs. Stube that contained misrepresentations regarding Xeljanz's safety. Citing to an opinion from the District of Minnesota that did not discuss the learned intermediary doctrine, Plaintiffs argue that today's drug-marketing environment requires heightened consumer protection because drug manufacturers directly target the public with advertisements for drugs.

The opinion that Plaintiffs' argument is premised on, *Witczak v. Pfizer, Inc.*, concerned whether the plaintiff's failure-to-warn claim was preempted by federal law. 377 F. Supp. 2d 726, 732 (D. Minn. 2005). *Witczak* did not discuss or apply the learned intermediary doctrine. *See generally id.* Moreover, *Witczak* did not apply Arkansas law, so the Court need not express an opinion on *Witczak*'s statement in dicta that heightened consumer protections are needed due to drug manufacturers' direct-marketing initiatives. Whether or not that sentiment is true, the Court must apply the learned intermediary doctrine as it exists in Arkansas. Decades ago, the Arkansas

Supreme Court recognized several public policy considerations underlying its decision to adopt the learned intermediary doctrine:

> First, a physician must prescribe the drug, the patient relies upon the physician's judgment in selecting the drug, and the patient relies upon the physician's advice in using the drug. That is to say that there is an independent medical decision by the learned intermediary that the drug is appropriate. Second, it is virtually impossible in many cases for a manufacturer to directly warn each patient. Third, imposition of a duty to warn the user directly would interfere with the relationship between the doctor and the patient.

West, 305 Ark. at 42, 806 S.W.2d at 613; *see also Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1097 (8th Cir. 2013) (discussing the same policy considerations).

Plaintiffs have cited to no Arkansas caselaw or statute holding that, irrespective of the learned intermediary doctrine, a drug manufacturer must directly warn a patient of a drug's risks. Moreover, the Court is unaware of any such authority. Rather, the policy considerations underlying the Arkansas Supreme Court's decision to adopt the learned intermediary doctrine appear to refute that argument. The Arkansas Supreme Court specifically opined that requiring drug manufacturers to directly warn the ultimate drug consumer would interfere with the doctor/patient relationship because patients rely on their doctors' expertise in selecting and using drugs. *West*, 305 Ark. at 42, 806 S.W.2d at 613. Consequently, the Arkansas Supreme Court adopted the learned intermediary doctrine and created an exception to the general duty to warn. Plaintiffs' argument would have the Court essentially ignore this exception. The Court declines to do so because it has long been the law in Arkansas that drug manufacturers can warn prescribing physicians of a drug's risks and rely on those learned physicians to adequately warn their patients.

Accordingly, Plaintiffs' claims fail as a matter of law to the extent that they seek to impose on Defendant a duty to directly warn the ultimate drug consumers of the risks of taking Defendant's

drugs.[8] Plaintiffs' claims should be dismissed to the extent that they are premised on Defendant's failure to directly warn Mrs. Stube, or the general public, of the risks of taking Xeljanz.

E. Fraud

Defendant argues that Plaintiffs' fraud claims fail as a matter of law because they do not satisfy Federal Rule of Civil Procedure 9(b). Specifically, Defendant argues that Plaintiffs have not pleaded the identity of the person who allegedly made false misrepresentations, the dates and locations of those false misrepresentations, or the specific content of the false misrepresentations. Plaintiffs respond that they are only required to allege the "core" factual basis of their fraud claims, which they have done by alleging that Defendant withheld critical safety data and medical literature and made various misrepresentations regarding Xeljanz's safety through advertisements, brochures, sales representatives, dossiers, and labels. Plaintiffs argue that their allegations put Defendant on notice as to the allegedly fraudulent conduct and, thus, their fraud claim is sufficiently pleaded.

To state a viable claim of fraud in Arkansas, a plaintiff must allege facts for the following five elements: "(1) a false representation, usually of a material fact; (2) knowledge or belief by the defendant that the representation is false; (3) intent to induce reliance on the part of the plaintiff; (4) justifiable reliance by the plaintiff; and (5) resulting damage to the plaintiff." *Allen v. Allison*, 356 Ark. 403, 418, 155 S.W.3d 682, 693 (2004). Furthermore, claims sounding in fraud must

[8] The Court notes that Defendant's memorandum brief also states that "each of Plaintiff's claims is barred by the [learned] intermediary doctrine" (ECF No. 19, p. 7), which seems to suggest that Defendant asks for the entire case to be dismissed pursuant to that doctrine. However, this does not square with the argument offered by Defendant on that issue, that Plaintiffs' claims should be dismissed to the extent that they are predicated on Defendant's alleged duty to warn Plaintiffs, or the public, of the risks of taking Xeljanz. To the extent that Defendant intended to argue for dismissal of Plaintiffs' entire complaint based on the learned intermediary doctrine, the Court finds that argument unavailing. Plaintiff's case is largely premised on allegations that Defendant failed to adequately warn Mrs. Stube's prescribing physician of the risks of taking Xeljanz, despite Defendant's knowledge of those risks. As previously discussed above, the Court will not weigh the evidence at this stage to determine whether that was indeed the case. Plaintiffs' claims are sufficiently pleaded with respect to an alleged failure to adequately warn Mrs. Stube's prescribing physician.

comply with the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) by pleading with particularity the circumstances surrounding the fraud. *Costner*, 317 F.3d at 888. This pleading standard "demands a higher degree of notice than that required for other claims. The claim must identify who, what, where, when, and how." *Id.* Rule 9 does not require a plaintiff to allege specific details of every alleged fraudulent claim forming the basis of the complaint, but a plaintiff must at least provide some representative examples in the manner outlined above to allow the defendant to respond specifically to the allegations. *U.S. ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir. 2006).

Taking Plaintiffs' well-pleaded allegations as true and drawing all reasonable inferences in their favor, the Court need not look past the "who" component because the Court agrees with Defendant that Plaintiffs' fraud claim does not satisfy Rule 9's specificity requirements. To satisfy Rule 9, Plaintiffs must specifically allege, *inter alia*, "the identity of the person allegedly committing fraud." *Roberts v. Francis*, 128 F.3d 647, 651 (8th Cir. 1997). Plaintiffs allege that Defendant made various misrepresentations regarding Xeljanz's safety. However, Plaintiffs' complaint does not identify any specific employee or agent of Defendant who made misrepresentations. At most, Plaintiffs allege generally that "sales representatives" made misrepresentations.

It is insufficient to allege generally that Defendant, a multinational corporate entity, committed fraud without identifying a specific employee or agent of Defendant who acted fraudulently. *See Joshi*, 441 F.3d at 556 (finding that a fraud claim was insufficiently pleaded, in part, because the plaintiff alleged that a hospital committed fraud but failed to identify any specific employees who participated in the fraudulent conduct); *Khaliki v. Helzberg Diamond Shops, Inc.*, No. 4:11-cv-0010-NKL, 2011 WL 1326660, at *4 (W.D. Mo. Apr. 6, 2011) (finding allegations

that a corporate defendant misrepresented its product to be insufficient under Rule 9(b)); *Gunderson v. ADM Inv'r Servs., Inc.*, No. C 96-3148-MWB, 1997 WL 570453, at *10 (N.D. Iowa Apr. 17, 1997) (dismissing fraud claims against corporate defendants, in part, because "no specific employees are identified whatsoever in the complaints, let alone what misrepresentations were made by a specific employee or agent").

The cases cited by Plaintiffs on this issue are inapposite because they involve properly pleaded fraud claims asserted against individuals who were specifically identified as the allegedly fraudulent actors. That is not the case here because Plaintiffs have not specifically identified any individual who made the alleged misrepresentations at issue in this case. Further, Plaintiffs also do not allege "the time [and] place . . . of the defendant's false representations." *Joshi*, 441 F.3d at 556-57. Accordingly, Plaintiffs' fraud claim is not pleaded with particularity as required by Rule 9(b) and should be dismissed.

F. Negligent Misrepresentation

Plaintiffs assert a claim of "negligent misrepresentation," alleging that Defendant breached a duty to disseminate accurate and adequate information on Xeljanz by making various misrepresentations with the intention of inducing reliance by prescribing physicians. Defendant argues that this claim should be dismissed because Arkansas does not recognize the tort of negligent misrepresentation. In response, Plaintiffs "agree to voluntarily dismiss their negligent misrepresentation claim." (ECF No. 22, p. 29). To date, however, Plaintiffs have not moved for voluntary dismissal of that claim, so the Court will dispose of it in this order.

The Court agrees with Defendant that Plaintiffs' negligent misrepresentation claim fails as a matter of law. The Arkansas Supreme Court has expressly refused to recognize an independent cause of action for negligent misrepresentation. *S. Cnty., Inc. v. First W. Loan Co.*, 315 Ark. 722,

726, 871 S.W.2d 325, 326 (1994). Thus, Plaintiffs cannot state a claim of negligent misrepresentation upon which relief may be granted. Plaintiffs' negligent misrepresentation claim should be dismissed.

G. Gross Negligence

Defendant asks the Court to dismiss Plaintiffs' claim of gross negligence, arguing that Plaintiffs' allegations, taken as true, amount to ordinary negligence at most and do not rise to the level required for gross negligence. Plaintiffs argue that their gross negligence claim should survive the pleading stage.

In short, negligence "is the failure to use ordinary care." *Spence v. Vaught*, 236 Ark. 509, 512, 367 S.W.2d 238, 240 (1963). Gross negligence goes a step further and "is the failure to use even slight care." *Id.* Stated differently, gross negligence is an "intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another." *IPSCO Tubulars, Inc. v. Ajax TOCCO Magnathermic Corp.*, 779 F.3d 744, 752 (8th Cir. 2015) (quoting *Doe v. Baum*, 348 Ark. 259, 278, 72 S.W.3d 476, 487 (2002)).

The Court finds that Plaintiffs have alleged enough for their gross negligence claim to survive the pleading stage. The section in Plaintiffs' complaint setting out the claim of gross negligence is scarce and largely mirrors Plaintiffs' allegations for their claim of ordinary negligence. However, elsewhere in their complaint, they allege that Defendant had a duty to test Xeljanz and adequately warn prescribing physicians of the drug's side effects. They allege that Defendant knew that Xeljanz caused unreasonably dangerous side effects to certain people, that Defendant had not disclosed this to prescribing physicians, and that consumers like Mrs. Stube would suffer injury if they took Xeljanz. They allege further that Defendant intentionally chose to continue manufacturing, marketing, and selling Xeljanz without any additional warnings,

despite knowing that the drug would harm certain consumers who take it. Thus, the Court is satisfied that Plaintiffs alleged that Defendant intentionally failed to "perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another." *Id.* At this stage, these allegations are enough to state a viable claim of gross negligence. Plaintiffs' gross negligence claim will not be dismissed.

H. Punitive Damages

Defendant asks the Court to dismiss Plaintiffs' request for punitive damages, arguing that the allegations in Plaintiffs' complaint, taken as true, do not rise to the level required to award punitive damages. Plaintiffs argue that their punitive damages request should survive the pleading stage.

The parties interchangeably characterize Plaintiffs' request for punitive damages as both a "claim" and a "request," but "punitive damages are not an independent cause of action in Arkansas." *Simpson v. Wright Med. Grp., Inc.*, No. 5:17-cv-0062-KGB, 2018 WL 1570795, at *10 (E.D. Ark. Mar. 30, 2018). Rather, punitive damages are a form of relief that may be sought for an underlying cause of action. *Id.*; *see also Bell v. McManus*, 294 Ark. 275, 277, 742 S.W.2d 559, 560 (1988) ("In the absence of an award for damages for the underlying cause of action, punitive damages are improper."). Thus, punitive damages are not a "claim" subject to a Rule 12(b)(6) motion to dismiss. *Benedetto v. Delta Air Lines, Inc.*, 917 F. Supp. 2d 976, 984 (D.S.D. 2013); *Sec. Nat'l Bank of Sioux City, Iowa v. Abbott Labs.*, No. 11-cv-4017-DEO, 2012 WL 327863, at *21 (N.D. Iowa Feb. 1, 2012). Consequently, the Court will not address the issue of punitive damages at this time.

I. Plaintiffs' Request to Amend Their Complaint

Plaintiffs ask, in the last sentence of their response, that if the Court is inclined to dismiss any of their claims, that it instead give them leave to amend their complaint pursuant to Federal Rule of Civil Procedure 15(a)(2). Defendant's reply does not acknowledge this request, but the Court must nonetheless address it. *See Pure Cnty., Inc. v. Sigma Chi Fraternity*, 312 F.3d 952, 956 (8th Cir. 2002) (stating that courts should not rule on a motion to dismiss without first addressing any pending motions for leave to amend).

Except in cases where a party may amend its complaint as a matter of course,[9] "a party may amend its pleading only with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). This is a liberal standard and courts "should freely give leave when justice so requires." *Doe v. Cassel*, 403 F.3d 986, 990 (8th Cir. 2005). However, there is no absolute right to amend a pleading. *Baptist Health v. Smith*, 477 F.3d 540, 544 (8th Cir. 2007).

Putting aside the issue of whether Plaintiffs' request for leave to amend their complaint was properly raised in a response brief rather than in a separate motion, Plaintiffs' request is what is known as a "conditional" request for leave to amend, which seeks leave to amend only if the court grants an opposing party's dispositive motion. *See Plymouth Cnty., Iowa ex rel. Raymond v. MERSCORP, Inc.*, 287 F.R.D. 449, 455 (N.D. Iowa 2012), *aff'd sub nom. Plymouth Cnty., Iowa v. Merscorp, Inc.*, 774 F.3d 1155 (8th Cir. 2014). A conditional request for leave to amend must offer more than a "*pro forma*" willingness to amend if the court finds the complaint to be insufficient, while simultaneously standing on the sufficiency of the complaint. *Id.* at 458. In other words, a proper conditional request for leave to amend must be accompanied by a proposed

[9] "A party may amend its pleading once as a matter of course within: (A) 21 days after serving it, or (B) if the pleading is one to which a responsive pleading is required, 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier." Fed. R. Civ. P. 15(a)(1). Neither of these instances apply in this case.

amended complaint or, at bare minimum, a statement of the substance of the proposed amendment. *In re 2007 Novastar Fin. Inc., Sec. Litig.*, 579 F.3d 878, 884-85 (8th Cir. 2009); *see also* Local Rule 5.5(e) (requiring any party moving to amend a pleading to both describe in detail what would be amended and attach to the motion a copy of the proposed amendment). Failure to offer either of these is a justifiable basis for denying a conditional request for leave to amend. *Novastar*, 579 F.3d at 884-85.

Plaintiffs' request for leave to amend offers only a "*pro forma*" willingness to amend. Plaintiffs neither offer a copy of their proposed amended complaint, nor do they describe the substance of their proposed amendments. They say only that their hypothetical amended complaint would "cure any pleading deficiencies." This is insufficient to preserve their right to amend. *Id.*; *see also* Local Rule 5.5(e). Consequently, assuming Plaintiffs' request for leave to amend their complaint constitutes a valid motion, it is denied.

IV. CONCLUSION

For the above-stated reasons, Defendant's motion to dismiss (ECF No. 18) is hereby **GRANTED IN PART AND DENIED IN PART**. Plaintiffs' claims of fraud and negligent misrepresentation are hereby **DISMISSED WITHOUT PREJUDICE**. Moreover, Plaintiffs' claims are **DISMISSED WITHOUT PREJUDICE** to the extent that they are premised on Defendant's alleged duty to directly warn Mrs. Stube and the public of the risks of taking Xeljanz. All other claims remain.

IT IS SO ORDERED, this 13th day of March, 2020.

/s/ Susan O. Hickey
Susan O. Hickey
Chief United States District Judge